

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached is captioned **"VERSION WITH MARKINGS TO SHOW CHANGES MADE."** As can be seen, no new matter has been added.

As such, entry of the above amendments is respectfully requested.

### **Rejections**

Claims 32-37 and 39-40 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Wang. In making this rejection, the Examiner asserts that the recited instructional element is not deemed to hold any patentable weight.

However, the Examiner has cited no case law or MPEP section to support this position. In fact, courts treat instructions for use, e.g., in the form of printed matter, as a separate element to be accorded patentable weight just like any other recited element.

The Federal Circuit in *In re Gulack*, 217 U.S.P.Q 401 (1983) held that:

"Differences between an invention and the prior art cited against it cannot be ignored merely because those differences reside in the content of the printed matter. n8 Under section 103, the board cannot dissect a claim, excise the printed matter from it, and declare the remaining portion of the mutilated claim to be unpatentable. The claim must be read as a whole."

Thus, printed matter that is an element of claim must accorded patentable weight just like any other element.

The *In re Gulack* court also explained that:

"Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability. Although the printed matter must be considered, in that situation it may not be entitled to patentable weight. "

Thus, only in those situations where the printed matter is not functionally related to the other elements of the claim will the printed matter not carry patentable weight. Importantly, if the printed matter is functionally related to the other elements of the claim, the printed matter does carry patentable weight and the printed matter must be considered in determining patentability, just like any other element of the claim.

One situation where printed matter was considered to be functionally related to the other elements of a claim is where the claim was directed to a measuring device and the printed matter on the side of the measuring device provided indications of the amounts of material in the measuring device. In this situation, the court found that the printed material was functionally related to the other elements of the claim because it told how to use the other elements of the claim. See *In re Miller*, 57 C.C.P.A. 809, 418 F.2d 1392, 164 U.S.P.Q. (BNA) 46. Similarly, the *In re Gulack* court found that numbers printed on bands in a mathematical device imparted patentability to the device in that they told how use the device in a way different from the prior art and therefore were functionally related to the device.

In the present case, the instructions are a separate and important element of the claimed kit because they tell how to use the components of the kit. Because the instructions tell how to use the other kit elements in a way that is different from the prior art, they are functionally related to the other kit elements. Since they are functionally related to the other kit elements, they must be accorded patentable weight just like the other kit elements. As such, the Examiner is in error in failing to accord the claimed instruction elements any patentable weight and must treat the claimed instruction element just like any other element.

Turning now to an analysis of whether the claimed invention (giving the instructional element its due consideration of holding patentable weight just like any other element), it is well established that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or

inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987), *cert. denied*, 481 U.S. 1052 (1987). *See also, Scripps Clinic and Research Foundation v. Genentech, Inc.*, 18 USPQ 2d 1001 (Fed. Cir. 1991).

In the present case, Wang fails to teach the instructional element of the present claims because Wang is concerned with an entirely different method. As such, Wang fails to teach each and every element of the claims.

Because Wang fails to teach each and every element of the claimed kit, e.g., the instructions, Wang fails to anticipate Claims 32-37 and 39-40 under 35 U.S.C. § 102(e) and this rejection may be withdrawn.

Claims 32-36 and 39-40 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Phillips. In making this rejection, the Examiner asserts that the recited instructional element is not deemed to hold any patentable weight.

As demonstrated above, in the present situation the instructional element holds patentable weight just like any other element.

Phillips fails to teach the instructional element of the present claims because Phillips is concerned with an entirely different method. As such, Phillips fails to teach each and every element of the claims.

Because Phillips fails to teach each and every element of the claimed kit, e.g., the instructions, Phillips fails to anticipate Claims 32-36 and 39-40 under 35 U.S.C. § 102(e) and this rejection may be withdrawn.

Finally, Claim 38 was rejection under 35 U.S.C. § 112, 2<sup>nd</sup> ¶. In view of the above amendment to this claim, this rejection may be withdrawn.

With respect to newly added Claims 41 to 48, these claims incorporate the limitation of Claim 38, which was not rejected over the prior art. As such, these claims are believed to be allowable.

**Conclusion**

The applicant respectfully submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Gordon Stewart at 650 485 2386. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-1078.

Respectfully submitted,

Date: 1.28.02

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Atty Dkt. No.: 10990638-2  
USSN: 09/690,173

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

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38. (Amended) The kit according to Claim 32, wherein the kit comprises ~~a first~~ an RNaseH- polymerase and ~~a second~~ an RNaseH+RNaseH+ polymerase.

Please add the following new claims:

--41. (New) A kit for use in linearly amplifying mRNA, said kit comprising:

- (a) an oligonucleotide promoter-primer comprising an RNA polymerase promoter sequence;
- (b) an RNaseH- polymerase; and
- (c) an RNaseH+ polymerase.

42. (New) The kit according to Claim 41, wherein said kit further comprises:

instructions to convert the mRNA to cDNA, and to then transcribe the cDNA into RNA in the presence of a reverse transcriptase that is rendered incapable of RNA-dependent DNA polymerase activity during this transcription step.

43. (New) The kit according to Claim 42, wherein the instructions include an instruction for inactivating the reverse transcriptase by heating.

44. (New) The kit according to claim 43, wherein the instruction for heating comprises an instruction to raise the temperature to between 55°C to 70°C for 5 to 60 minutes.

45. (New) The kit according to Claim 44, wherein the instruction to raise the temperature comprises an instruction to raise the temperature to 65 °C.

46. (New) The kit according to Claim 41, wherein said kit further comprises MMLV-RT.

47. (New) The kit according to Claim 46, wherein said kit further comprises an RNA polymerase.

48. (New) The kit according to Claim 47, wherein said RNA polymerase is T7 RNA polymerase. --